510(k) Summary

MAY - 4 2012

Submitted By: Kensey Nash Corporation
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Contact Person: Susan Pileggi
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Date Prepared: March 16, 2012

510(k): **K120141**

Device:

Trade Name:	**Kensey Nash Bone Void Filler XC**
Common/Usual Name:	Filler, Bone Void, Calcium Compound
Proposed Classification:	21 CFR 888.3045 MQV Class II

Predicate Device: K060917: Kensey Nash Bone Void Filler

Device Description:

The Kensey Nash Bone Void Filler XC is a mixture of beta tricalcium phosphate and polylactic acid. The product will be provided gamma sterilized for one time use in a healthcare facility. The products are supplied in a variety of shapes ranging from pre-formed cylinders, granules, cubes, blocks, and wedges ranging up to 25mm in diameter and up to 30cc in volume.

The safety and effectiveness of this device for use in chondral and osteochondral defects have not been established. This device is not intended for the replacement of articular cartilage.

Intended Use:

The Kensey Nash Bone Void Filler XC is intended to be gently packed into the bony voids or gaps of the extremities and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. These defects may be created from traumatic injury to the bone or surgically created osseous defects. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. The device may be combined with sterile fluids such as saline or autogenous blood products such as blood or bone marrow aspirate. The addition of the autogenous products does not alter the performance of the device.

Technological Characteristics:

The technological characteristics of Kensey Nash Bone Void Filler XC are identical to the Kensey Nash Bone Void Filler cleared per K060917. The device and predicate are designed to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. There are no new design changes that could affect the safety or effectiveness of the device.

Performance Data:

The non-clinical testing submitted in the predicate device (K060917) included biocompatibility, physical properties testing, compressive strength, and an animal study. This testing remains applicable to this submission.

Substantial Equivalence:

The Kensey Nash Bone Void Filler XC is substantially equivalent to the predicate device with regard to intended use, indications for use, operating principle, design, materials, packaging, sterilization, and manufacturing process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kensey Nash Corporation
% Ms. Susan Pileggi
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735 Pennsylvania Drive
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MAY 4 2012

Re: K120141
Trade/Device Name: Kensey Nash Bone Void Filler XC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: March 19, 2012
Received: March 20, 2012

Dear Ms. Pileggi

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the device's labeling:

> "The safety and effectiveness of this device for use in chondral and osteochondral defects have not been established. This device is not intended for the replacement of articular cartilage."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Kensey Nash

Indications For Use Statement

510(k) Number: K120141

Device Name: Kensey Nash Bone Void Filler XC

Indications For Use:

The Kensey Nash Bone Void Filler XC is intended to be gently packed into the bony voids or gaps of the extremities and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. These defects may be created from traumatic injury to the bone or surgically created osseous defects. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. The device may be combined with sterile fluids such as saline or autogenous blood products such as blood or bone marrow aspirate. The addition of the autogenous products does not alter the performance of the device.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) **(Per 21 CFR 801 Subpart C)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120141